

United States Department of Agriculture Animal and Plant Health Inspection Service Plant Protection & Quarantine 4700 River Road Riverdale, MD 20737

Permit to Move Live Plant Pests, Noxious Weeds, and Soil

Importation

Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system

PERMITTEE NAME: Dr. Charles Lee

PERMIT NUMBER: P526P-19-03103

APPLICATION

P526-190224-021

ADDRESS: 800 Buchanan Street FACILITY 5194

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Albany, CA 94710 NUMBER:
MAILING ADDRESS: 800 Buchanan Street HAND CARRY: Yes

Albany, CA 94710

DATE ISSUED: 07/15/2019

PHONE: 510-559-5858

FAX: EXPIRES: 07/15/2022

DESTINATION: United States Department of Agriculture-ARS, 800

Buchanan Street, Albany, CA 94710

DESIGNATED

CA, El Segundo; CA, South San Francisco; FL, Miami

(Cargo, DHI, End Ev. LIPS, etc.): GA, Atlanta: NI

PORTS: (Cargo, DHL, Fed Ex, UPS, etc.); GA, Atlanta; NJ, Linden; NY, Jamaica; TX, Humble; WA, SeaTac

Emden, 141, Juniarea, 172, Hemore, W71, Seatte					
Under the conditions specified, this permit authorizes the following:					
Regulated Article	Life Stage(s)	<u>Intended Use</u>	Shipment Origins	Originally Collected	Culture Designation
Bacillus safensis	Petri dishes/culture tubes	Research - Greenhouse (growth chamber and lab included)	Pakistan	Originally Collected from Foreign Locations	Bacillus safensis strain AN4
Bacillus tropicus	Petri dishes/culture tubes	Research - Greenhouse (growth chamber and lab included)	Pakistan	Originally Collected from Foreign Locations	Bacillus tropicus strain AN5
Citrobacter sp.	Petri dishes/culture tubes	Research - Greenhouse (growth chamber and lab included)	Pakistan	Originally Collected from Foreign Locations	Citrobacter sp. strain AN6

SPECIAL INSTRUCTIONS TO INSPECTORS

See permit conditions below

This permit authorizes Charles Lee and Ahmad Nadeem of the United States Department of Agriculture-ARS in Albany, California, to hand-carry or move the organisms via passenger baggage into the United States in accordance with the hand-carry conditions below.

DHS CBP INSPECTORS - HAND CARRY INSTRUCTIONS

THIS PERMIT HAS BEEN APPROVED ELECTRONICALLY BY THE FOLLOWING PPQ HEADQUARTER OFFICIAL VIA EPERMITS.	DATE
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- 1) For all hand carry events, the port of entry must have received hand carry requests at least 20 days in advance of the arrival of passenger(s), including the date and time of arrival and method of transport (maritime, land border, air) directly from CBP-OFO-APTL, originally provided by USDA-APHIS. The port of entry for hand carry does not need to appear as a designated port on the permit; this official notice containing the information listed above authorizes the port listed on the notice as a destination port for this hand carry event.
- 2) For all hand carry events, a valid PPQ permit number or the PPQ permit must be provided in order to identify the designated hand carrier.
- 3) If the two conditions above are met and the CBP Agriculture Specialist confirms that all hand carried materials/organisms are securely packaged as per the permit conditions, the permitted regulated material/organisms may be released for immediate transport by the designated hand carrier to the destination address listed on the permit.
- 4) If the permitted regulated materials/organisms arrive by hand carrying, in personal luggage, or by personal automobile without a hand carry authorization as specified in the permit, CBP may seize and destroy the package or send it to the nearest PPQ Plant Inspection Station for further processing. The permit holder is responsible for all costs incidental to such actions. If forwarding the shipment is not possible, contact the Pest Permit Staff at the number below.

DHS CBP INSPECTORS - SHIPMENT BY BONDED CARRIER

- 1) Confirm that the carrier of the shipment imported under this USDA PPQ 526 permit is commercially bonded.
- 2) Confirm that the imported shipment has a valid USDA PPQ Form 599 Red/White label attached to the exterior for routing to a USDA APHIS PPQ Inspection Station or other "Designated Port" as stated on the Permit. A valid label will have the permit number, expiration date, label number, and address of a USDA APHIS PPQ Plant Inspection Station/Designated Port. PLEASE NOTE: In the event of a shipment of bulk container with discrete units, a single PPO Form 599 Red/White label may be used.
- 3) Validate the permit in ePermits using the CBP search feature.
- 4) If a valid PPQ Form 599 Red/White label is not attached to the exterior of the package or the label has been covered or is otherwise not legible, then forward to the nearest USDA APHIS PPO Plant Inspection Station.
- 5) If the address on the airway bill does not match the address on the PPQ Form 599 Red/White label then forward the package to the nearest USDA APHIS PPO Plant Inspection Station/designated port shown on the PPQ Form 599 label. All costs associated with rerouting misaddressed packages will be assumed by the permit holder.

APHIS PPQ INSPECTORS at PIS - High-Risk Microbial

PPQ HEADQUARTER OFFICIAL VIA EPERMITS.

Follow the instructions in the Plant Inspection Station Manual for High-Risk Microbial, Unknown Organisms (Diagnostics) Red and White Labeled Packages (must be opened in a biosafety cabinet; see procedures for handling on page 3-7-40). For questions or concerns, contact the USDA APHIS PPQ Pest Permit Branch in Riverdale, MD, at 301-851-2046, toll free 866-524-5421.

THIS PERMIT HAS BEEN APPROVED ELECTRONICALLY BY THE FOLLOWING DATE

WARNING: Any alteration, forgery or unauthorized use of this Federal Form is subject to civil penalties of up to \$250,000 (7 U.S.C.s 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C.s 1001)



PERMIT GUIDANCE

- 1) Receipt or use of foreign isolates or samples from countries under sanctions requires specific permission from the U.S. Department of Treasury; please refer to https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx
- 2) This permit does not authorize movement or release into the environment of genetically engineered organisms produced with the regulated organisms described in this permit. Importation, interstate movement, and environmental release of genetically engineered plant pests require a different permit issued under regulations at 7 CFR part 340. Any unauthorized interstate movement or environmental release, including accidental release, of a regulated GE organism would be a violation of those regulations. Additional guidance and contact information for APHIS Biotechnology Regulatory Services, can be found at: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology.
- 3) If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to http://www.aphis.usda.gov/import export/animals/animal import/animal imports an approducts.sh tml
- 4) If a human pathogen is identified, please refer to the CDC Etiologic Agent Import Permit Program at http://www.cdc.gov/od/eaipp/
- 5) This permit does not fulfill the requirements of other federal or state regulatory authorities. Please contact the appropriate agencies, such as the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, the APHIS Biotechnology Regulatory Services, or your State's Department of Agriculture to ensure proper permitting.
- 6) If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

PERMIT CONDITIONS

USDA-APHIS issues this permit to Dr. Charles Lee of the United States Department of Agriculture-ARS in Albany, California. This permit authorizes the importation of pure cultures of the listed regulated organisms from various researchers in Pakistan to California.

This permit also authorizes the use of the regulated materials/organisms for laboratory, greenhouse, and growth chamber research in the listed APHIS approved Containment Facility, #5194.

Charles Lee and Ahmad Nadeem are authorized to hand-carry the regulated organisms into the United States in accordance with the hand-carry conditions below.

 This permit is issued by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). It conveys APHIS regulations and requirements for the material(s) listed on this permit. It does not reduce or eliminate your legal duty and responsibility to comply with all other applicable Federal and State regulatory requirements.

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- The permit number or a copy of the permit must accompany the shipment.
- You must be an individual at least 18 years old, or legal entity such as partnership, corporation, association, or joint venture.
- You are legally responsible for complying with all permit requirements and permit conditions.
- The regulated material and shipping container(s) are subject to inspection by officials of Custom and Border Protection (CBP) and APHIS. CBP or APHIS officials may require the shipment to be treated, seized, re-exported, or destroyed (in part or whole). You will be responsible for expenses.
- If you violate any applicable laws associated with this permit, you may face substantial civil or criminal penalties. We may cancel all current permits and deny future permit applications.
- Without prior notice and during reasonable hours, authorized Federal and State Regulators must be allowed to inspect the conditions associated with the regulated materials/organisms authorized under this permit.

2. The permit holder must:

- maintain a valid PPQ526 permit so long as the regulated materials/organisms are alive or viable.
- not assign or transfer this permit to other persons without APHIS PPQ authorization,
- maintain an official permanent work assignment, residence, or affiliation at the address on this permit,
- notify the Pest Permit Staff as soon as possible of any change in the permit holder's work assignment, residence, or affiliation,
- notify the Pest Permit Staff of the receipt of unauthorized and/or misdirected shipments of regulated materials/organisms,
- adequately mitigate environmental impacts resulting from unauthorized release of regulated materials/organisms and notify the Pest Permit staff immediately if one occurs,
- notify the Pest Permit Staff if the facility is damaged/destroyed or if you wish to decommission the facility,

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• destroy all regulated materials/organisms prior to departure from the organization unless other arrangements are confirmed by the Pest Permit Staff.

Notifications to the Pest Permit Staff must be made via 866-524-5421 or pest.permits@usda.gov within one business day of the event triggering a notification.

3. This permit does not authorize movement or use of organisms listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agriculture Select Agent Services (AgSAS) immediately by phone at 301-851-3300 option 3, and within seven (7) days submit APHIS/CDC Form 4A (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, AgSAS; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at: https://www.selectagents.gov/resources/APHIS-CDC_Form_4_Guidance_Document.pdf). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002. For a complete list of Select Agents please visit: https://www.selectagents.gov/selectagentsandtoxinslist.html
Select agents include: Peronosclerospora philippinensis (Peronosclerospora sacchari), Coniothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines), Ralstonia

Coniothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines), Ralstonia solanacearum, Rathayibacter toxicus, Sclerophthora rayssiae, Synchytrium endobioticum, Xanthomonas oryzae, Bacillus anthracis, Brucella abortus, Brucella melitensis, Brucella suis, Burkholderia mallei, and Burkholderia pseudomallei.

4. All persons working with the listed regulated materials/organisms must be informed of these permit conditions. Anyone working with these materials/organisms must agree to adhere to and sign/initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/APHIS but must be readily accessible and made available to Federal and State regulators upon request.

Note: these conditions may be copied and stored electronically for electronic signature and initialing provided that the permit number, authorized materials/organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

5. All packages for transport must minimally consist of both inner/primary and outer/secondary packages securely sealed so that both are effective barriers to escape or unauthorized dissemination of the listed materials/organisms. The inner/primary package(s) will contain all regulated materials/organisms and must be cushioned and sealed in such a way that it remains sealed during shock, impact, and pressure changes that may occur. The outer/secondary shipping container must

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be rigid and strong enough to withstand typical shipping conditions (dropping, stacking, impact from other freight, etc.) without opening.

6. After PPO issues this 526 permit, you will need to request Red/White labels (PPO Form 599) at least 5 days in advance of your shipping date. If you applied for your permit online using ePermits, you may request the labels using the My Shipments/Labels feature. Otherwise, send your request to Redandwhitelabelrequest@usda.gov. All email requests must come from the permit holder or designee. If requested by the designee, the permit holder must be copied on all requests. Specify the approved port as listed on the permit and the total number of labels needed. You may request additional labels the same way.

Packages without labels on the exterior may be refused entry.

Review label instructions at: https://www.aphis.usda.gov/planthealth/shipping-red-white-labels

You are responsible for instructing your shipper to carefully follow these instructions. You are responsible for each import shipping label issued under this permit.

- 7. Upon receipt, all packages must be opened within a Class II or III biosafety cabinet in the approved containment facility identified above to prevent the potential dissemination of the package contents. Cultures must be in a sealed container during transport to or within the permit holder's assigned research facilities.
- 8. HAND CARRY PART 1 OF 2

The following conditions apply to all authorized hand carry events. Note that no PPQ-issued labels are required for hand carry events.

a) At least 20 days prior to each hand carry event, the permit holder or designee must notify the PPO Permit Compliance Officer by email. In the subject line of the email, write "Notification of Hand Carry - Permit # xxxx":

For pests/pathogens, federal noxious weeds/parasitic plants, and host plant materials, please use: PPQRegulatedOrganismsHandCarryRequest@usda.gov

The email must contain the following information:

- hand carrier's name and permit number
- anticipated first port of entry into the United States
- date and time of arrival and method of transport (maritime, land border, air)

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- description of the regulated material/organism and packaging used for transport
- travel plans from the first port of arrival to the final destination

The PPQ Permit Compliance Officer will notify the Customs and Border Protection (CBP) Agricultural Specialist at the port of entry to document and facilitate the entry of the regulated material/organism.

If you have domestic (connecting) air travel plans, please contact the Transportation Security Administration (TSA) prior to arrival into the U.S.: TSA Contact Center Telephone: 1-866-289-9673; Email: TSA-ContactCenter@tsa.dhs.gov. Passengers can request special assistance with the screening process via the TSA Contact Center. Although special handling may be requested when traveling with fragile or sensitive items, TSA must conduct sufficient screening to ensure all property does not present a security threat. For more information visit www. TSA.gov.

Only the person(s) whose name(s) is/are listed on the issued permit is/are authorized to hand-carry. Charles Lee and Ahmad Nadeem are authorized to hand-carry the regulated organisms into the United States in accordance with the hand-carry conditions.

- b) The hand carrier must ensure the following:
 - All materials/organisms must be packaged as described in the permit conditions.
 - Packaging material must be free of insects, noxious weeds, and other plants pests and must be treated as described in the permit conditions before discarded or reused.
 - Hand-carried regulated materials/organisms must fit in the plane's overhead bin or under the seat. Hand-carried materials/organisms are not to be checked as baggage/luggage, and must remain on or in close proximity to one's person.

9. HAND CARRY PART 2 OF 2

c) The hand carrier must declare the regulated material/organism at the port of entry. The hand carrier must present acceptable personal identification documents to CBP upon request. The hand carrier must also present a copy and/or permit number of the valid PPQ Permit that authorizes the hand carry.

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- d) In the event that a problem is detected, CBP may seize and destroy the package or send it to the nearest PPQ Plant Inspection Station for further processing. The permit holder is responsible for all costs incidental to such actions.
- e) The authorization to hand carry is only for the regulated material/organism identified in the permit. The presence of unauthorized regulated materials/organisms is a permit violation.
- f) After CBP confirmation and clearance through the first port of entry into the U.S., the hand carrier will not open or modify the package (including removal of anything applied to the package by CBP or another Federal Agency) until it arrives at the authorized facility. The hand carried regulated material/organism must be transported directly to the containment facility authorized in the permit. In the event that circumstances beyond the carrier's control cause a significant deviation in transport, the carrier must contact the PPQ Permit Compliance Officer at 866-524-5421 (pests/pathogens, federal noxious weeds/parasitic plants, soil, and host plant materials) or 877-770-5990 (for restricted or prohibited plant material).
- g) Within 24 hours of the first business day of the regulated material/organisms' arrival at the facility, an independent third party (e.g. containment facility director, departmental chair, campus biosafety officer, etc.) must notify the PPQ Permit Compliance Officer via email that the shipment remained sealed until arrival. The notification must include what regulated material/organism was imported, its origin, permit number, date of arrival, and quantity. In the subject line of the email, please write: "Notification of Hand Carry Arrival Permit # xxxx". See Hand Carry Part 1(a) above for the list of e-mail addresses to use for the notification.
- Failure to notify the PPQ Permit Compliance Officer may result in loss of hand carry privileges. A PPQ inspector may visit the facility to confirm the arrival of the package and its contents.
- 10. All research activities, plant inoculations and subsequent disease development must occur within the APHIS approved Containment Facility identified above that has been inspected and found adequate for containment of the organisms received under this permit. Access to this facility must be restricted to authorized personnel.
- 11. Plant inoculations are authorized in the greenhouses and growth chambers associated with the APHIS approved Containment Facility listed above.
- 12. Vector transmission is not permitted under this authorization. Only mechanical inoculation of plants is permitted.
- 13. Measures to control potential insect vectors (e.g. black lights, yellow sticky boards, insecticides) must be in place.
- 14. Greenhouses must be screened to minimize presence of insect vectors.

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Osmond Baron

On 15/2019



15. Standard Operating Procedures (SOPs) must be filed with, and approved by, the APHIS PPQ Pest Permit Staff at: email: pest.permits@usda.gov; phone: 866-524-5421; fax: 301-734-8700; address: 4700 River Road, Unit 133, Riverdale, MD 20737. All contact information must be kept current and the SOPs must be dated. If requirements in the permit conditions are more restrictive than the SOPs, permit conditions take precedence. APHIS PPQ must approve any changes to the SOPs before implementation.

A list of all persons with access to the containment facility must be maintained and available upon request by Federal or State Regulatory Officials.

All persons working with the regulated material/organism(s) must be trained on, and implement the permit conditions, and all APHIS approved SOPs governing the facility listed above.

- 16. Modifications to the containment facility or any changes that affect the containment of the regulated materials/organisms must be approved by APHIS prior to making changes. Please contact the Pest Permit Staff (email: pest.permits@usda.gov; phone: 866-524-5421; address: 4700 River Rd., Unit 133, Riverdale, MD 20737; Fax: 301-734-8700).
- 17. Records must be kept of all organisms maintained under this permit. Minimally the record will consist of the name of the organism identified to the lowest taxon possible, the country, or US state/territory, where each isolate was collected, and the date the isolate was received. These records must be made available to Federal and State regulators upon request.
- 18. When not working with the regulated materials/organisms, you must store and/or maintain them within the APHIS approved containment facility identified above. All stored regulated materials/organisms must be kept in a locked area with access limited to authorized personnel.
- 19. DEVITALIZATION AND WASTE DISPOSAL

All regulated materials/organisms and all items coming in direct contact or exposed to the regulated materials/organisms must be sterilized/sanitized/decontaminated prior to removal from the authorized containment facility. This includes all items from shipping, culturing, care, and maintenance of these regulated materials/organisms. This requirement includes but is not necessarily limited to: packaging directly exposed to the regulated materials/organisms, substrates (culture media, soil, plant materials (food materials or host plants)), leftover/unused/unneeded live cultures, and dead specimens/cultures unless specified otherwise in the permit.

Prior to disposal or reuse, you must treat all contaminated and all potentially contaminated materials by one of the following methods, either alone or in combination:

1) autoclaved (see protocol below), 2) disposed of off-site by a facility holding a valid PPQ compliance agreement (organisms and/or contaminated waste must be stored in sealed containers prior to pick up by this company), 3) incinerated, 4) immersed in 5,250-6,000 PPM sodium hypochlorite solution (1 part fresh household bleach to 9 parts water) for at least 20 minutes, or 5)

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immersed in 70 percent alcohol for at least 30 minutes. Treated waste will be double bagged prior to disposal.

Other sterilization methods are only allowed with prior written agreement from the USDA/APHIS PPQ Pest Permit Staff.

If using an autoclave the following protocol must be used:

- a. Waste must be autoclaved at 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes at 15 psi.
- b. Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
- c. The autoclave must be calibrated according to the manufacturer's instructions annually and a commercially available biological indicator kit that uses bacterial spores of Geobacillus stearothermophilus that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every three months.

OR

The autoclave must be calibrated according to the manufacturer's instructions every two years and a commercially available biological indicator kit that uses bacterial spores of Geobacillus stearothermophilus that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every two weeks.

- d. A written record of the calibration and the biological indicator tests must be maintained. You must follow the manufacturer's instructions for the Geobacillus sterothermophilus and if any growth is observed, you must have the autoclave serviced and retested before it is used again for the regulated articles/organisms listed on this permit.
- 20. As an alternative to the DEVITALIZATION AND WASTE DISPOSAL requirements listed above, devitalization/destruction of organisms and infected material may be conducted off site by a facility holding a valid PPQ compliance agreement prior to disposal. Vendor may or may not be in the same state. All organisms, contaminants and/or packaging materials must be in sealed containers during transport to this waste management facility in order to prevent any unauthorized dissemination of the regulated articles.
- 21. There is to be no further movement or distribution of the listed regulated materials/organisms within the United States and its territories unless the recipient holds, or is named as a responsible party on a valid PPQ526 permit for receipt of such materials/organisms.

END OF PERMIT CONDITIONS

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